

H' quantitated for the amount of DNA (total content) in the sample DNA by such means as electrophoresis, UV irradiation or absorption so that an adequate amount of DNA may be added in accordance with the excessiveness.--

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IN THE CLAIMS

Please cancel claims 2, 6, 9, 10, and 12 without prejudice to or disclaimer of the subject matter recited therein.

The claims have been amended as follows:

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H2 3. (Four Times Amended) A nucleic acid assay process according to claim 13, wherein said mutated or polymorphic target DNA which is the same as said labeled standard DNA and which is present in said sample DNA is quantitated by evaluating the degree of exchange of the complementary strands between said sample DNA and said labeled standard DNA at the selected excessiveness of said sample DNA, wherein said exchange occurs at a higher frequency when said mutated or polymorphic target DNA is the same as the labeled standard DNA, and said label intensity is reduced.

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H3 7. (Three Times Amended) A nucleic acid assay process

according to claim 13, wherein the labeled standard DNA is prepared by amplification using a primer having introduced therein a region capable of binding to a solid support.

H3  
cont  
8. (Three Times Amended) A nucleic acid assay process according to claim 13, wherein the labeled standard DNA is prepared by chemical synthesis.

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H-1  
13. (Four Times Amended) A nucleic acid assay process for identifying and/or quantifying a mutation or polymorphism in a double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said particular region of said analyte nucleic acid which is present in said specimen to prepare said double stranded sample DNA for competitive hybridization, wherein said sample DNA

comprises both mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a detection limit for said mutated or polymorphic target DNA, wherein when the detection limit for the target DNA present in said sample DNA is A/B, the excessiveness of said sample DNA is at least B/A, and wherein A/B is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA and A is at least  $3.6 \times 10^{-6} \mu\text{g}$ ;

Hyd. cont.  
adding an excessive amount in  $\mu\text{g}$  of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under conditions which allow for hybridization of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said labeled standard DNA in the competitive hybridization is calculated as the value of B/A,

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during

#4  
cont. competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.

[Please add the following claims:]

#5 14. A nucleic acid assay process for identifying and/or quantifying a mutation or polymorphism in a double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said particular region of said analyte nucleic acid which is present in said specimen to prepare said double stranded sample DNA for competitive hybridization, wherein said sample DNA comprises both mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a theoretical value in  $\mu\text{g}$  for the amount of said mutated or polymorphic target DNA in said sample DNA, wherein the

amount in  $\mu\text{g}$  of said mutated or polymorphic target DNA is expressed as A, and the total amount in  $\mu\text{g}$  of said sample DNA is B, such that A/B is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA;

As cont.  
adding an excessive amount in  $\mu\text{g}$  of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under conditions which allow for hybridization of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said labeled standard DNA in the competitive hybridization is calculated as the value of B/A,

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.

15. A nucleic acid assay process for identifying and/or

quantifying a mutation or polymorphism in a double stranded sample DNA, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying a particular region of an analyte nucleic acid to prepare said double stranded sample DNA for competitive hybridization, wherein said sample DNA comprises both mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a theoretical value in  $\mu\text{g}$  for the amount of said mutated or polymorphic target DNA in said sample DNA, wherein the amount in  $\mu\text{g}$  of said mutated or polymorphic target DNA is expressed as A, and the total amount in  $\mu\text{g}$  of said sample DNA is B, such that  $A/B$  is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA;

adding an excessive amount in  $\mu\text{g}$  of said sample DNA to said labeled standard DNA, which is calculated as the value of  $B/A$ ;

allowing competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under

conditions wherein said wild-type DNA does not hybridize with said labeled standard DNA,

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.